REMARKS

A. Amendments in the specification

Paragraph 1 on page 4 is amended to replace "WO 94/07568" with "WO 94/07468" in order to correct a typographical error. The cited document was correctly cited as WO 94/07468 in the Information Disclosure Statement submitted on February 17, 2004. The Examiner's consideration of that IDS is hereby acknowledged.

B. Amendments in the claims

Following amendment as requested herein, the following claims are pending in the present application: Claims 2–7, 9 and 16.

Claims 1, 8 and 10–15 are canceled without prejudice.

Claim 1 is canceled as redundant over Claim 9. A "Swiss-form" claim such as Claim 1 as originally filed, reciting use of a composition in preparing a medicament or pharmaceutical composition for a particular therapeutic method, is generally accepted to provide support for the therapeutic method in question, comprising administration of said compound. In the present case, the method in question is found near the end of Claim 1 as originally filed, *viz.*, "treatment of Parkinson's disease." Claim 9 is more expressly drawn to the therapeutic method and is accordingly retained as the primary independent claim herein.

Claims 2–7 are amended to depend directly or indirectly from Claim 9 in place of Claim 1, and thus now recite "The method of" an antecedent claim.

Claims 8 and 10–15 are canceled as redundant over Claim 16.

Opportunity has been taken, in amending the claims, to correct typographical errors, to rephrase where it has been desirable to do so for enhanced clarity, and to present subject matter where necessary in terms more in accordance with standard U.S. claim drafting practice. For example, by reciting in Claim 7 that the composition "forms" a donor phase rather than "is used in" the donor phase, it is clearer that the donor phase is the recited composition rather than a physical portion of the device.

No new matter is added, and no changes in inventorship are believed to result from the present amendment.

RESPONSE TO OFFICE ACTION DATED MARCH 23, 2007

1. Rejection under 35 U.S.C. §112

Claims 7–8 and 11–16 are rejected under 35 U.S.C. §112, second paragraph, as being indefinite for allegedly failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The present Action asserts that it is unclear by the wording of the claims what exactly the donor phase is. Claims 7 and 16, as amended herein, specify that the composition forms the donor phase comprising the drug and the chloride salt.

Claims 1–8 and 10–16 are rejected for allegedly failing to set forth any steps involved in the method/process. Each of Claims 2–7 and 16 are, by amendment herein, made dependent directly or indirectly from Claim 9, which is not subject to the present rejection.

Claims 1, 8 and 10–15 are now canceled and the present rejection is therefore moot with respect to these claims.

In light of the above remarks, withdrawal of the present rejection under 35 U.S.C. §112, second paragraph is respectfully requested.

2. Rejection under 35 U.S.C. §101

Claims 1–8 and 10–16 are rejected under 35 U.S.C. §101 for recitation of a use, without setting forth any steps involved in the process. Following amendment of Claims 2–7 and 16 to depend directly or indirectly from Claim 9, not subject to the present rejection, and cancellation of Claims 1, 8 and 10–15, this rejection is moot. Withdrawal of the present rejection under 35 U.S.C. §101 is respectfully requested.

3. Rejection under 35 U.S.C. §103(a)

Claims 1–4, 6, 7, 9 and 10 are rejected under 35 U.S.C. §103(a) as allegedly obvious over Lauterback *et al.* (US 2003/0027793) in view of Panchagnula *et al.* (Curr. Opin. Chem. Biol. (2000) 4:468–473) and Suzuki *et al.* (US 6,416,503). This rejection is respectfully traversed. Following cancellation herein of Claims 1 and 10, the present rejection is moot with respect to these claims. With respect to Claims 2–4, 6, 7 and 9 that remain pending herein, Applicant respectfully submits that the Office has failed to meet its burden of making out a *prima facie* case of obviousness.

No admission is made herein that any document constitutes prior art to the present

invention. It is particularly noted that the Lauterback and Suzuki documents are not statutory prior art against the present invention, having published after or within no more than one year before the priority filing date of the present application. Applicant reserves the right to disqualify one or both of these documents as prior art. However, even if one or both of these documents did represent prior art, a *prima facie* case of obviousness over these documents could not be sustained, as shown below.

According to MPEP 2143, to establish a *prima facie* case of obviousness, three criteria must be satisfied. Absence of any one of these criteria is sufficient to overcome an allegation of *prima facie* obviousness: (1) there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings; (2) there must be a reasonable expectation of success; and (3) the prior art reference (or references when combined) must teach or suggest all the claim limitations.

Three documents are combined in the present Action in order to arrive at the present ground of rejection. The Examiner argues that it would have been obvious to one of ordinary skill in the art at the time of the invention to combine the teaching of Lauterback, relating to a method of making a transdermal patch containing rotigotine hydrochloride to treat Parkinson's disease, with the teachings of Panchagnula relating to transdermal delivery of drugs via iontophoresis, including a patch, and Suzuki relating to use of sodium chloride in an iontophoretic device. The Examiner makes the assertion that "Lauterback teaches ... rotigotine hydrochloride as the active ingredient" (emphasis added). Applicant respectfully disagrees with this assertion. Lauterback, in fact, relates to a transdermal therapeutic system containing rotigotine in free base form. Specifically, at paragraph **[0031]**, Lauterback states that "[u]nless expressly indicated otherwise, any references to rotigotine in the context of this invention and the claims of this application mean rotigotine in the form of its free base." Although the Preparation Example of Lauterback does utilize rotigotine hydrochloride as a starting material, this is reacted with NaOH to provide an ethanolic solution of rotigotine in the form of the free base (see last line of paragraph **[0038]**).

According to the Panchagnula abstract, iontophoresis is primarily used for delivery of large and charged molecules. Because the rotigotine free base delivered by the transdermal

patch of Lauterback is not a large and charged molecule, one of ordinary skill would not be motivated to combine the teachings of Lauterback with those of Panchagnula and Suzuki. Indeed, the requirement in Lauterback that rotigotine be in free base form teaches away from such a combination.

Even if, *arguendo*, motivation did exist to combine Lauterback with Panchagnula and Suzuki, *prima facie* obviousness would still require a reasonable expectation of success. As stated in the present application as filed at pages 4–5, several approaches to develop a system for iontophoretic administration of the dopamine agonists R-apomorphine and ropinirole have been described, with results at the lower end of the therapeutic concentration range. In view of the discouraging experiences with iontophoretic delivery of apomorphine and ropinirole, one of skill in the art would not have had a reasonable expectation of success in iontophoretic delivery of another dopamine agonist, namely rotigotine.

Thus, the present rejection cannot be sustained because a *prima facie* case of obviousness has not been established. Failure of *prima-facie* obviousness is shown at least by lack of motivation to combine the cited documents, in light of teaching away by Panchagnula. Alternatively, failure of *prima-facie* obviousness is shown at least by lack of reasonable expectation of success, based for example on poor results with other dopamine agonists.

The above remarks apply to all pending claims, including Claim 9. Notwithstanding the Examiner's remarks with respect to Claims 2–4, 6 and 7, these claims each embody all the limitations of Claim 9 from which they depend and are therefore nonobvious at least for the same reasons that Claim 9 is nonobvious. If an independent claim is nonbovious under 35 U.S.C. § 103, then any claim depending therefrom is nonobvious. MPEP 2143.03. Likewise, Claim 16, rejected in the present Action as dependent on a rejected claim, is nonobvious.

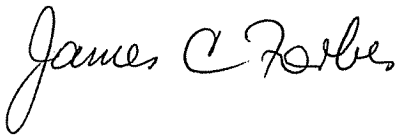
4. Conclusion

It is believed that all of the stated grounds of rejection are properly traversed, accommodated or rendered moot herein. Applicant therefore respectfully requests that the Examiner reconsider and withdraw all presently outstanding rejections. It is believed that a full and complete response has been made to the present Action and that the application is in condition for allowance.

Should any issues remain, the Examiner is invited to call the undersigned at the telephone number given below.

Respectfully submitted,

HARNESS, DICKEY & PIERCE, P.L.C.



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